

Amended Claims

1. Use of the nucleic acid of SEQ ID NO:1 or SEQ ID NO:3, fragments or variants thereof, in determining expression of mRNA in selected target tissue(s) for diagnosing orofacial clefting.
2. Use of the nucleic acid of SEQ ID NO:1 or SEQ ID NO:3, fragments or derivatives thereof, in determining the presence of DNA mutations in patients suffering from, or suspected to be suffering from orofacial clefting.
3. A polypeptide or a protein comprising an epitope for an antibody or a protein modified by one or more amino acid modifications and comprising an epitope, or a fragment modified or unmodified comprising an epitope for a tissue repair protein encoded by SEQ ID NO:2 or SEQ ID NO:4, for use in diagnosing orofacial clefting.
4. A delivery vehicle comprising the nucleic acid molecule as defined in either claim 1 or 2 and/or a polypeptide as defined in claim 3, which optionally is in the form of a suspension.
5. A delivery vehicle according to Claim 4 which is adapted to deliver said nucleic acid molecule or polypeptide to a selected tissue.
6. Antibodies against the polypeptide according to Claim 3.
7. Antibodies according to Claim 6 which are monoclonal.
8. Use of antibodies, fragments or derivatives thereof according to either Claim 6 or 7 in the diagnosis of orofacial clefting.

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- 5 9. A method for detecting the antibodies according to either Claim 6 or 7 in a sample, comprising contacting with the sample immobilised antibody against a protein or protein fragment of SEQ ID NO:2 or SEQ ID NO:4, which antibody has bound thereto a labelled ligand comprising a protein or protein fragment of SEQ ID NO:2 or SEQ ID NO:4, and detecting labelled ligand bound to immobilised antibody or labelled ligand bound to antibody in the sample.
- 10 10. A method for the treatment of orofacial clefting comprising administering to a patient suffering from orofacial clefting the nucleic acid molecule as defined in either claim 1 or 2 and/or the polypeptide as defined in claim 3.
- 15 11. A method for the treatment of wounds and/or tissue repair comprising administering to a patient suffering from a wound and/or tissue damage the nucleic acid molecule as defined in either claim 1 or 2 and/or the polypeptide as defined in claim 3.
- 20 12. A method of treatment according to either Claim 10 or Claim 11 wherein said nucleic acid molecule and/or polypeptide is administered by the incorporation of said nucleic acid molecule into a delivery vehicle according to either of Claims 4 or 5.
- 25 13. A nucleic acid as defined in either claim 1 or 2 and/or the polypeptide as defined in claim 3 for use as a pharmaceutical.
- 30 14. Use of the nucleic acid as defined in either claim 1 or 2 and/or the polypeptide as defined in claim 3 for the manufacture of a medicament for the treatment of orofacial clefting and/or wound healing and/or tissue repair.
15. A method of producing a transgenic non-human mammal comprising disrupting a gene, or the effective part thereof, the gene encoding at least one tissue repair protein and comprising the nucleic acid sequence as set forth in SEQ ID NO:3.
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16. A method according to Claim 15 wherein the transgenic non-human mammal is a rodent.

17. A method according to either of Claims 15 or 16 wherein the transgenic non-human mammal is a mouse.

18. A reporter gene construct based on the promoter region of a gene, or effective part thereof encoded by SEQ ID NO:1 or SEQ ID NO:3 or fragment or variant thereof.

19. Use of a reporter gene construct based on the promoter region of a gene or effective part thereof, encoded by SEQ ID NO:1 or SEQ ID NO:3 in the detection/screening of pharmaceuticals and/or other compounds and their potential teratogenic effects.

20. A cloned nucleic acid molecule encoding a tissue repair protein contained in a Yeast Artificial Chromosome species designated as AB 1380 YAC-CP1 and deposited with NCIMB Limited of Aberdeen, Scotland (UK) under accession number NCIMB 41005.

21. An isolated nucleic acid encoding a tissue repair protein, the nucleic acid may be selected from the group consisting of:

- (a) DNA having the nucleotide sequence given herein as SEQ ID NO:1 (which encodes the protein having the amino acid sequence given herein as SEQ ID NO:2), and which encodes a tissue repair protein;
- (b) nucleic acids which hybridize to DNA of (a) above (e.g., under stringent conditions) and which encode a tissue repair protein; and
- (c) nucleic acids which differ from the DNA of (a) or (b) above due to the degeneracy of the genetic code, and which encode a tissue repair protein encoded by a DNA of (a) or (b) above.

22. An isolated nucleic acid encoding a tissue repair protein, the nucleic acid may be selected from the group consisting of:

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- (a) DNA having the nucleotide sequence given herein as SEQ ID NO:3 (which encodes the protein having the amino acid sequence given herein as SEQ ID NO:4), and which encodes a tissue repair protein;
- (d) nucleic acids which hybridize to DNA of (a) above (e.g., under stringent conditions) and which encode a tissue repair protein; and
- (e) nucleic acids which differ from the DNA of (a) or (b) above due to the degeneracy of the genetic code, and which encode a tissue repair protein encoded by a DNA of (a) or (b) above.
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23. A pharmaceutical formulation comprising the nucleic acid sequence of SEQ ID NO:1 or SEQ ID NO:3 fragments or variants or products thereof, and a physiologically acceptable excipient, diluent or carrier.

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